REMARKS

According to the above amendments, claim 43 has been amended. Claims 43-67 remain in this application with claims 57-67 presently withdrawn from further consideration as being drawn to a non-elected invention. Thus, claims 43-48 and 50-56 are currently being examined. No claim has been allowed.

Claim Rejection - 35 USC § 112

Written Description Requirement

It is noted that the presently pending claims, claims 43-48 and 50-56 stand as being rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. In the Examiner's view, the application does not contain sufficient examples to convey to one skilled in the art at the time the application was filed, that the inventor had possession of the claimed invention. This rejection is respectfully traversed for reasons that follow.

More particularly, it appears that the Examiner has objected that only one example of each of the passenger peptide binding moieties including (mb-SCF), virus (retrovirus), packaging cell line (based on 293T), bioactive agent (β-galactosidase) and targeting cell line (Mo7e) has been provided in the application as filed.

The specification as filed may contain but one specific experimental example as referred to by the Examiner in providing

the example mentioned above, however, the specification indeed does contain and convey a great deal more relevant information. It should be recognized that the specification also teaches further examples of each of the passenger peptide binding moiety, virus, packaging cell line, bioactive agent and targeting cell line, each of which will be discussed.

Passenger peptide binding moiety

The specification defines the passenger peptide moiety on page 8 as a peptide with a biding moiety that is incorporated into a viral particle during viral budding. The "passenger" has a particular activity and can be any peptide that is capable of binding to other molecules. Examples of passenger peptides including antibodies and growth factors (see pages 14 and 15).

Virus

The specification describes a number of different viruses as being capable of use in the claimed invention. Page 7, last paragraph and pages 11-13 describe examples of enveloped viruses including retroviruses, pox viruses; orthomyxoviruses and rhabdoviruses.

Packaging cell line

The specification describes multiple packaging cell lines that are suitable for use in the claimed invention. For example, pages 6-7 and 30-31 describe examples of packaging cell types and include NIH/3T3, CHO, L929, FLY and Phoenix.

Bioactive agent

The specification defines bioactive agents on page 10 and describes a number of different bioactive agents suitable for use in the invention on pages 13 and 22-28. Examples of suitable bioactive agents include growth factors, enzymes, cytotoxic agents and antisense nucleotide sequences.

Targeting cell line

The specification describes multiple cell types that could be targeted by viral particles bearing passenger peptides on their surface. Examples of such cells are described on pages 19-20 (see table), 21-22, 37, 38-39 and include haemopoietic stem cells, epithelial stem cells and cancer cells (from various different tissues).

In view of the above, applicant remains convinced that the specification as filed easily contains sufficient information so that the skilled artisan would appreciate that the above-listed alternatives to the experimental example clearly satisfy the written description requirement with respect to the claimed subject matter. Noting also that one must take into consideration and appreciate that the level of understanding of one skilled in the art is quite high, applicant believes the present specification contains more than an adequate written description commensurate with U.S. patent practice to support the present claims. Reconsideration and withdrawal of the rejection

is respectfully requested.

Enablement

The Examiner has also rejected claims 43-48 and 50-56 as not being fully enabled. In particular, the Examiner believes that the specification does not provide working examples regarding non-retroviral particles and the effect of incorporation of passenger peptides on the properties of the virus.

The claims are limited to viruses that bud from the packaging cell, therefore limiting them to viruses with lipid envelopes. Applicant believes that it is known to those in the art that lipid enveloped viruses are assembled and undergoing budding from a lipid membrane in an almost identical manner. For example, the fundamental difference between retroviruses and other viruses is in the manner in which they replicate their genetic material, and not the mechanism in which they bud from host cells.

Accordingly, the skilled person would know that different lipid enveloped viruses would behave in an almost identical manner in relation to both their mechanism of budding and the incorporation of proteins as passengers into their envelope. Any minor changes to the methods that were required in order to adapt the use for non-retroviral would be only of a routine nature to the skilled person that works with the particular virus that will be used.

In addition, and as further support, an extract from a

virology textbook that describes the assembly of enveloped viruses, in which the process of assembly and budding is described and shown to be very similar in different viruses at pages 84-85 is attached to this paper as Exhibit A. In this regard, the inventor is aware that further data also may be available in the literature.

Applicant is of the opinion that given the present specification, in view of the level of ordinary skill in the art, the skilled artisan would clearly be able to make and use the claimed invention without undue experimentation. Applicant believes that the degree of unpredictability in the art is not such that undue experimentation would be necessary in view of the teachings of the specification and that one would be able to practice the invention based on the present disclosure. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claim Rejection - 35 USC § 102

The Examiner has rejected claims 43-48 and 54-56 under 35 USC § 102(a) as being anticipated by Jiang et al (Jiang et al, Cell-type-specific gene transfer into human cells with retroviral vectors that display single-chain antibodies. *J Virol.* 72(12): 10148-56, 1998) for reasons enumerated. This rejection is respectfully traversed.

Applicant believes that the amendment to claim 43 that excludes the displayed passenger peptide from being a chimeric or

fusion protein overcomes any lack of novelty with respect to Jiang et al (1998). The reference only describes the display of foreign (passenger) peptides on viral particles when the foreign peptide is part of chimeric display protein that includes a viral display protein portion.

In view of the present clear difference, the Examiner is respectfully requested to withdraw this rejection.

Claim Rejection - 35 USC § 103

The Examiner has rejected claim 51 under 35 USC § 103(a) as being unpatentable over Jiang et al (1998) in view of Dropulic et al (USPN 6,114,141, issued September 5, 2000). In addition, claims 52-53 have been rejected under 35 USC § 103(a) as being unpatentable over Jiang et al (1998) in view of Guber et al (USPN 5,691,177, issued November 25, 1997). These rejections are respectfully traversed.

It should be noted that in light of the amendment made to claim 43, dependent claims 51, 52 and 53 are consequently also limited to non-chimeric/fusion protein peptides being displayed on the viral surface. As discussed above, the claims as amended do not require the use of viral display proteins, which was previously though to be the only way of displaying biologically functional foreign peptides on viral particles.

None of Jiang, Dropulic or Guber provide any indication that it is possible to display foreign peptides on viral particles, let alone that foreign peptides may retain their biological

function when displayed.

The applicant has found that the presently claimed invention obviates the necessity for engineering of the viral envelope proteins to display the protein of choice on the viral surface. This provides a variety of advantages including freeing up a variety of retroviral envelope proteins, which can be used in their native form for purposes other than display of foreign proteins.

A combination of the cited documents does not provide the claimed invention as none of the documents describe or suggest the possibility of non-chimeric/fusion foreign peptides being displayed on viruses.

Therefore, claim 51 is not obvious over a combination of Jiang et al and Dropulic et al and claims 52-53 are not obvious over a combination of Jiang et and Guber et al.

Consequently, applicant requests that this rejection be reconsidered and withdrawn.

In view of the above amendments, taken together with the remarks herein, applicant is of the opinion that the claims as presently constituted are properly supported by the specification both with respect to the written description requirement and are clearly enabled. In addition, it is believed that the claims distinguish over the prior art cited by the Examiner, either taken singularly or in combination.

Reconsideration and allowance of the claims is respectfully requested.

Should issues remain that, in the opinion of the Examiner, could be resolved by telephone interview, he is invited to contact the undersigned attorney in an effort to resolve same and expedite prosecution of this application.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment in response to the Official Action of September 5, 2006, Appendix A, a Petition for a three-month extension of time, a check in the amount of $1020.00 and a Transmittal Letter in application Serial No. 10/520,745, filed on August 22, 2005, of Colin M. Casimir, entitled "METHODS OF MAKING VIRAL PARTICLES HAVING A MODIFIED CELL BINDING ACTIVITY AND USES THEREOF" are being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, postage prepaid, on March 5, 2007.

Barbara L Davis

Barbara L. Davis
on behalf of C. G. Mersereau
Attorney for Applicant

Date of Signature: March 5, 2007